

### **III. REMARKS/ARGUMENTS**

#### **A. Status of the Application**

Claims 1, 5, 8, 11-22 and 36 are pending. Claims 2-4, 6-7, 9-10 and 23-35 have been cancelled. Claims 1, 11, 15 and 36 have been amended in accordance with 37 C.F.R. §1.121(c)(1). Favorable consideration and allowance of claims 1, 5, 8, 11-22 and 36 in view of the foregoing amendments and the following remarks are respectfully requested.

#### **B. Withdrawal of Rejections**

Applicants appreciate the withdrawal of the previous rejections of claims 1, 5, 8 and 10-22 under 35 U.S.C. §112, second paragraph and under 35 U.S.C. § 103(a) over U.S. Patent No. 6,642,277 to Howard et al.

#### **C. Rejection under 35 USC § 103(a) over Fleischner ‘533 in view of Brand and further in view of Cho ‘314**

Claims 1, 5, 8, 10-22 and 36 stand rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 6,291,533 to Fleischner (“Fleischner ‘533”) in view of Brand et al. (An Outstanding Food Source of Vitamin C, The Lancet, Vol. 320 Issue 833, p. 873) (“Brand”) and further in view of U.S. Publication No. 2002/0192314 to Cho et al. (“Cho ‘314”). As noted above, claim 10 has been cancelled. Insofar as it may be applied to the present claims, this rejection is respectfully traversed.

Independent claim 1 is directed to an antioxidant composition that includes a flavonoid and a mixture of at least two forms of vitamin E as primary ingredients and bush plum pulp and skin, green tea extract and grape skin extract as secondary ingredients. The primary ingredients are present in the composition in an amount of 30% to 85% by weight and the secondary ingredients are present in the composition in an amount of 15% to 70% by weight. Also, the flavonoid and the mixture of vitamin E forms are present in the composition in a weight ratio of from 40/60 to 90/10 percent while the grape skin extract and the green tea extract are present in the composition in a weight ratio of from 60/40 to 80/20 percent. According to claim 1, the

flavonoid is selected from the group consisting of a flavone, a flavonol, an isoflavone, an isoflavonol, an analogue thereof, a pharmaceutically acceptable salt thereof, and a mixture thereof. Also according to claim 1, the at least two forms of vitamin E are selected from the group consisting of alpha, beta, delta, epsilon, gamma, zeta, eta, xi1, xi2, and sigma tocopherols, and alpha, beta, delta and gamma tocotrienols, and derivatives thereof. Further, according to claim 1, the bush plum pulp and skin comprises 5% vitamin C, the green tea extract comprises 35-95% polyphenols, and the grape skin extract comprises 30-82% polyphenols.

Each of claims 5, 8, 11-14, 18-20 depends, directly or indirectly, from and therefore includes at least the same elements as claim 1.

Independent claim 15 is directed to an antioxidant composition that includes:

quercetin;  
a mixture of alpha, beta, delta, and gamma tocopherols;  
grape skin extract comprising 30-82% polyphenols;  
green tea extract comprising 35-95% polyphenols; and  
bush plum pulp and skin comprising 5% vitamin C.

According to claim 15, the quercetin and the mixture of tocopherols account for between 30% and 85% by weight of the antioxidant composition. Also according to claim 15, the quercetin and mixture of tocopherols are present in the composition in a weight ratio of from 40/60 to 90/10 percent while the grape skin extract and the green tea extract are present in the composition in a weight ratio of from 60/40 to 80/20 percent.

Each of claims 16-17 and 21-22 depends, directly or indirectly, from and therefore includes at least the same elements as claim 15.

Independent claim 36 is directed to an antioxidant composition that includes quercetin, a mixture of alpha, beta, delta, and gamma tocopherols, grape skin extract comprising 30-82% polyphenols, green tea extract comprising 35-95% polyphenols, bush plum pulp and skin comprising 5% vitamin C, and a carrier comprising gum acacia, xanthan gum, gum tragacanth, gum ghatti, and aloe vera gel extract. According to claim 36:

- the quercetin and the mixture of tocopherols are primary ingredients and the primary ingredients are present in the composition in an amount of from 30% to 85% by weight;

- the bush plum pulp and skin, the green tea extract, and the grape skin extract are secondary ingredients and the secondary ingredients are present in the composition in an amount of from 15% to 70% by weight;
- the quercetin and the mixture of tocopherols are present in the composition in a weight ratio of from 40/60 to 90/10 percent;
- the grape skin extract and the green tea extract are present in the composition in a weight ratio of from 60/40 to 80/20 percent; and
- the quercetin, the mixture of tocopherols, the grape skin extract, the green tea extract, and the bush plum pulp and skin are present in the composition in a weight ratio of 1:2 to 2:1, with respect to the carrier.

In *KSR Int'l. Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739 (2007), the Court stated that "a patent composed of several elements **is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.** Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a **reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.** This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *Id.* at 1741 (emphasis added).

As the PTO recognizes in MPEP § 2142:

*... The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness...*

For the reasons set forth below, it is respectfully submitted that Fleischner '533 in view of Brand and further in view of Cho '314 do not produce a prima facie case of obviousness for claims 1, 5, 8, 11-22 and 36.

**1. All words in the claim have not been considered**

MPEP § 2143.03 states that "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art." Quoting *In re Wilson*, 424 F.2d 1382, 1385

(CCPA 1970). However, in the present matter, it is respectfully submitted that all of the words in the claims have not been considered. For example, independent claims 1, 15 and 36 recite antioxidant compositions that include:

- a flavonoid, such as quercetin as in claims 15 and 36;
- a mixture of at least two forms of vitamin E, such as alpha, beta, delta, and gamma tocopherols as in claims 15 and 36;
- bush plum pulp and skin comprising 5% vitamin C;
- green tea extract comprising 35-95% polyphenols; and
- grape skin extract comprising 30-82% polyphenols.

The flavonoid and mixture of vitamin E forms are present in the composition in an amount of from 30 to 85% by weight and in a weight ratio of from 40/60 to 90/10 percent. The bush plum pulp and skin, the green tea extract and the grape skin extract are present in the composition in an amount of from 15 to 70% by weight. The grape skin extract and the green tea extract are present in the composition in a weight ratio of from 60/40 to 80/20 percent. According to claim 36, the antioxidant composition further includes a carrier comprising gum acacia, xanthan gum, gum tragacanth, gum ghatti and aloe vera gel extract wherein the quercetin, the mixture of tocopherols, the grape skin extract, the green tea extract, and the bush plum pulp and skin are present in the composition in a weight ratio of 1:2 to 2:1, with respect to the carrier.

Fleischner '533 discloses various dietary supplement compositions that are said to be designed to be responsive to specific blood types and to be "useful in achieving and maintenance of a healthy status". (Fleischner '533, Abstract and Column 2, lines 33-40). Fleischner '533 discloses a dietary supplement composition that is alleged to be designed for humans with Type A blood which includes:

- 50-500 mg. of Vitamin C
- 25-400 IU of Vitamin E (as d-alpha-tocopheryl succinate and 50% from natural d-alpha-, d-beta-, d-gamma-, and d-delta-tocopherols)
- 100-400 mcg. of folate
- 10-50 mcg. of Vitamin B-12
- 25-200 mg. of Hawthorn berry standardized extract
- 50-250 mg. of quercetin dihydrate

- 50-200 mg. of milk thistle seed extract
- 10-50 mg. of alfalfa leaf
- 10-50 mg. of Aloe vera leaf gel 200:1 concentrate
- 10-100 mg. of Burdock root
- 10-50 mg. of Fenugreek seed
- 10-100 mg. of ginger root
- 50-200 mg. of green tea leaf extract
- 25-300 mg. of St. John's Wort standardized extract
- 10-50 mg. of slippery elm bark
- 10-50 mg. of skull cap root
- 10-50 mg. of parsley leaf
- 10-100 mg. of dandelion root
- 10-50 mg. of chamomile flower
- 10-50 mg. of sarsaparilla root
- and 25-100 mg. of pueraria root extract.

(Fleischner '533, Column 7 line 53 to Column 8 line 37).

Accordingly, the dietary supplement composition designed for humans with Type A blood disclosed by Fleischner '533 includes quercetin dihydrate, at least two forms of Vitamin E, and green tea leaf extract, but does not include bush plum pulp and skin or grape skin extract. Also, with reference to claim 36, Fleischner '533 discloses that the composition designed for humans with Type A blood includes Aloe vera leaf gel 200:1 concentrate but does not disclose a carrier that includes gum acacia, xanthan gum, gum tragacanth, gum ghatti and aloe vera gel extract.

As further noted in the Office Action (Page 4, lines 3-4), Fleischner '533 "does not teach a source of vitamin C and does not disclose a composition additionally comprising bush plum pulp and skin comprising 5% vitamin C." Brand is cited for its disclosure that the pulp and skin of the bush plum is an outstanding source of Vitamin C.

Also as noted in the Office Action (Page 4, lines 16-17), Fleischner ‘533 “does not disclose a supplement additionally comprising grape skin extract comprising 30-82% polyphenols.” Cho ‘314 is cited for its disclosure of a dietary supplement comprising grape skin extract comprising polyphenols of between 25 and 100%.

The Office Action proposes that it would have been obvious to one of ordinary skill in the art to modify the composition disclosed by Fleischner ‘533 with the teachings of: (a) Brand by using the edible parts of bush plum as a source of vitamin C, and (b) Cho ‘314 by using grape skin extracts in 25-100% polyphenols to gain the advantages of the antioxidant properties of grape skin. Regardless of the combination of Fleischner ‘533, Brand and Cho ‘314, and without conceding the propriety of such combination, Applicant notes that claims 1, 15 and 36 require that the flavonoid and mixture of vitamin E forms are present in the claimed compositions in a weight ratio of from 40/60 to 90/10 percent and that the grape skin extract and the green tea extract are present in the claimed compositions in a weight ratio of from 60/40 to 80/20 percent. None of Fleischner ‘533, Brand or Cho ‘314 disclose or suggest these claim limitations.

In view of the foregoing, Applicant submits that a prima facie case of obviousness over Fleischner ‘533, in view of Brand and in further view of Cho ‘314 has not and cannot be established with respect to claims 1, 15 and 36. Accordingly, Applicant respectfully requests that the rejection of claims 1, 5, 8, 11-22 and 36 under U.S.C. § 103(a) over Fleischner ‘533, in view of Brand and in further view of Cho ‘314 be withdrawn.

**2. The elements being combined have not been shown to produce a predictable result**

MPEP § 2143.01 (III) states that the “mere fact that references can be combined does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art.”

As noted in the Office Action, Fleischner ‘533 does not disclose or suggest an antioxidant composition that includes a flavonoid and a mixture of vitamin E forms that are present in the composition in a weight ratio of from 40/60 to 90/10 percent. The Office Action also states that optimization of a result-effective variable is ordinarily within the skill of one in the art and that a result-effective variable is one that has well-known and expected results. The Office Action then

concludes that the selection of the percentage by weight of any ingredient in the claimed antioxidant composition is a result effective variable.

Contrary to what is stated in the Office Action, the weight ratio of from 40/60 to 90/10 percent of the flavonoid to the mixture of vitamin E forms in the claimed compositions is not a result effective variable. Instead, and as shown in FIG. 2 and as discussed in paragraph [0031], a synergistic effect is realized in terms of antioxidant capacity when the flavonoid and the mixture of vitamin E forms are present in the claimed compositions in a weight ratio of from 40/60 to 90/10 percent. In this context, the synergistic effect is realized as an antioxidant capacity that is greater than the additive effect that would be expected from the addition of the flavonoid and the mixture of vitamin E forms to the composition. As such, the enhanced antioxidant capacity achieved by the claimed compositions that include the flavonoid and the mixture of vitamin E forms in a weight ratio of from 40/60 to 90/10 percent is unexpected and therefore not a result effective variable. Such unexpected results are not predicable and, therefore, in accordance with MPEP § 2143.01 (III) would not be obvious to one of ordinary skill in the art.

Furthermore, and as noted above, the purported combination of Fleischner '533, Brand and Cho '314 does not disclose or suggest the claimed compositions in which the grape skin extract and the green tea extract are present in a weight ratio of from 60/40 to 80/20 percent. As shown in FIG. 3 of the present application and as disclosed in paragraphs [0032] and [0015], the optimal ratio of grape skin extract to green tea extract is 60/40 to 80/20 percent. The combination of Fleischner '533, Brand and Cho '314 is completely devoid of any disclosure or suggestion of a composition that includes grape skin extract and green tea extract in the optimal ratio of 60/40 to 80/20 percent. Accordingly, there is no reason why the combination of the grape skin extract of Cho '314 with the composition that includes green tea extract according to Fleischner '533 in the way claimed, i.e. at a weight ratio of from 60/40 to 80/20 percent would present a predictable result.

In view of the foregoing, Applicant submits that a prima facie case of obviousness over Fleischner '533, in view of Brand and in further view of Cho '314 has not and cannot be established with respect to claims 1, 15 and 36. Accordingly, Applicant respectfully requests that the rejection of claims 1, 5, 8, 11-22 and 36 under U.S.C. § 103(a) over Fleischner '533, in view of Brand and in further view of Cho '314 be withdrawn.

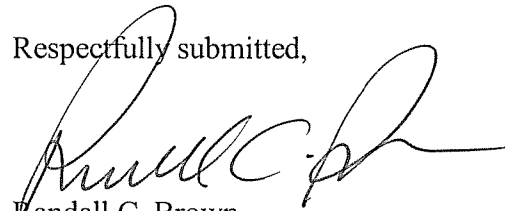
**Conclusion**

It is believed that all matters set forth in the Office Action have been addressed. Favorable consideration and allowance of claims 1, 5, 8, 11-22 and 36 are respectfully requested. Should the Examiner deem that an interview with Applicants' undersigned attorney would expedite consideration of the claims, the Examiner is invited to call the undersigned attorney at the telephone number indicated below.

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Respectfully submitted,



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